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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,232	11/22/2005	Bret Cooper	1392/10/19 PCT/US	2354
25297 7590 04/15/2008 JENKINS, WILSON, TAYLOR & HUNT, P. A. 3100 TOWER BLVD., Suite 1200 DURHAM, NC 27707				
EXAMINER				
PAGE, BRENT T				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,232

Applicant(s)

COOPER, BRET

Examiner

BRENT PAGE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
4a) Of the above claim(s) 1-53, 56 and 58 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 54, 55 and 57 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date 4/2007, 8/2007
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

The reply filed by Applicant on 01/08/2008 is hereby acknowledged.

Claims 1-58 are pending. Claims 1-53, 56 and 58 have been withdrawn. Claims 54-55 and 57 are examined on the merits below.

Specification

Applicant has amended the specification and the objections to the specification for containing embedded hyperlinks are hereby withdrawn.

Claim Rejections - 35 USC § 112

In response to the claim amendments and arguments by Applicant, the rejection of claims 54-55 and 57 under 35 U.S.C. 112 second paragraph as being indefinite is hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-55 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of modulating cell proliferation in any plant by transforming a plant cell with nucleic acid that encodes a polypeptide that need bind only a fragment of the polypeptide encoded by SEQ ID NO:210.

In contrast, the specification, while giving the guidance for transforming plants with distinct nucleic acids as outlined in Table 7 that encode polypeptides that bind to SEQ ID NO:210, does not reasonably provide enablement for transforming a plant with any nucleic acid that encodes any polypeptide that binds SEQ ID NO:210. Furthermore the specification provides no guidance for so much as a single example of transforming any species of plant with any of the above mentioned nucleic acid sequences that actually results in a plant with modulated cell proliferation as compared to a non-transformed plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Although the specification identifies and describes putative polypeptide sequences that bind the amino acid sequence of SEQ ID NO:210 encoded by SEQ ID NO:209, the specification does not provide any guidance for modulating proliferation of a plant cell. While it is proposed that proteins that bind the cyclin protein *may* have a role in cell cycle and thus have an effect on cell cycle modulation, no working examples and no guidance is given that would reasonably enable one of skill in the art to actually modulate cell proliferation in a plant cell. There is no correlation shown in the specification that reasonably guides one of skill in the art to distinguish between functioning embodiments and non-functioning embodiments that are encompassed by the claims as written. It is expected that many proteins may prove to bind SEQ ID NO:210 that may not have any relation to cell cycle functions, and that even ones that do have some

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functional capacity may not prove capable of modulating proliferation of a plant cell merely by transforming a plant with the nucleic acid that encodes the identified polypeptide. In order to provide enablement for the full scope of the claims, there must be some guidance in the specification that would lead one of skill in the art to reasonably expect success when evaluating all species within the scope of the claims. As the claims are currently written, literally billions of sequences could potentially bind to SEQ ID NO:210, especially absent specified binding conditions, and most of these embodiments would be expected to be non-functioning embodiments.

Given the state of the art and the lack of clear guidance in the specification as discussed above, it would be undue experimentation for one of skill in the art to evaluate all polypeptide fragments and the nucleic acids that encode them for their ability to modulate plant cell proliferation in a transgenic plant as broadly claimed.

Claims 54-55 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for modulating proliferation of a plant cell comprising introducing into any plant any nucleic acid sequence that encodes any polypeptide that binds any fragment of SEQ ID NO:210 in a yeast two hybrid assay.

In contrast the specification does not contain any working examples of modulation proliferation of a plant cell with any of the disclosed nucleic acid sequences from the specification. The specification also does not describe what structures of the binding polypeptides would be necessary for the claimed function.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

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[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in *Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111*.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 recites "an enhancement of a rate" which does not distinctly point out what Applicant regards as their invention. By using the term "a rate" it is unclear whether the rate is one of cell growth, and if it is, whether it is specific to the transformed cell or not. It is suggested to use the term "the rate" if Applicants intend to limit the rate to that of the claimed cell. New Matter should be avoided.

Claim 55 also recites "an isolated nucleic". It is unclear what group of transformed cells is being compared to the untransformed cells. New Matter should be avoided in correcting the claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-55 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorlach et al (US20020059663).

The claims are broadly drawn to a method for modulating proliferation of a plant cell comprising introducing into any plant any nucleic acid sequence that encodes any polypeptide that binds any fragment of SEQ ID NO:210 in a yeast two hybrid assay.

Gorlach et al disclose the transformation of an Arabidopsis plant with a syntaxin-related protein (see claims 1-7 and Table 1, for example). The instant specification shows that a syntaxin-related protein binds SEQ ID NO:210, and inherent property of the protein, absent evidence to the contrary. The result of the modulation of cell proliferation is also an inherent property that would result

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from the transformation of the plant as described by Gorlach et al, absent any evidence to the contrary.

The reply filed by Applicant on 01/08/2008 was fully considered and as a result of the claim amendments when taken together with Applicant's arguments, results in the original rejection of claims 54-55 and 57 under 35 U.S.C. 102(e) being hereby withdrawn.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Phuong T. Bui/
Primary Examiner, Art Unit 1638